UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WISCONSIN

PROMEGA CORPORATION,

Plaintiff,

and

MAX-PLANCK-GESELLSCHAFT zur FORDERUNG der WISSENSCHAFTEN E.V.,

Case No. 10-cv-281-bbc

Involuntary Plaintiff,

v.

LIFE TECHNOLOGIES CORPORATION, INVITROGEN IP HOLDINGS, INC., and APPLIED BIOSYSTEMS, LLC,

Defendants.

PROFFER OF ANTICIPATED TESTIMONY BY ARTHUR EISENBERG

If called as a witness in this matter Arthur Eisenberg's testimony would be in substance as follows:

Background

- He is Professor and Chairman of the Department of Forensic and Investigative Genetics at the University of North Texas Health Science Center.
- Member of numerous forensic governing bodies and forensics associations
    - Currently appointed by the Texas Attorney General to serve on the Texas Forensic Science Commission,
    - Member of the Texas Crime Laboratory Director's Association
    - Member of the National Institute of Justice Missing Persons/Mass Disaster Committee.
- In 2011, he was awarded the Paul L. Kirk Award from the Criminalistics Section of the American Academy of Forensic Sciences.

- In 1998, he received the Director of the FBI's Award in Recognition of Efforts and Significant Contribution During the Past Ten Years of DNA Forensic Testing at the FBI.
- He has been an author on over 70 peer-reviewed publications in the area of DNA forensic science.

Development of the Forensics Field

- In 1994, Congress passed the DNA Identification Act
    - Gave the Director of the FBI authority to establish a DNA Advisory Board to develop national standards for forensic DNA testing and databasing laboratories.
    - Nobel laureate Dr. Joshua Lederberg was appointed as the chair of the committee.
    - He was appointed to the board and later succeeded Dr. Lederberg as the chairman in 1998.
- As part of the DNA Advisory Board, he helped shape the FBI's Quality Assurance Standards for Forensic DNA Testing Laboratories and the Quality Assurance Standards for Convicted Offender DNA Databasing Laboratories.
    - These documents have become benchmarks for assessing the quality practices and performances of DNA laboratories throughout the country and have since been combined into the current **Quality Assurance Standards for Forensic DNA Testing Laboratories ("QAS")**, a true copy of which is attached hereto as **EXHIBIT 1**.
    - Federal DNA Advisory Board's statutory term expired, and the responsibility for recommending revisions of these Quality Assurance Standards was transferred to the Scientific Working Group on DNA Analysis Methods (SWGDAM).
    - SWGDAM updates have included, for example, expanded requirements on validation and continuing education.
    - He has been an Invited Member of SWGDAM from 1989 to present.
- Forensic research, training, and education are all necessary in order to qualify, accredit, and validate the scientific methodologies, forensic scientists, DNA laboratories, and STR kits used in forensic DNA analysis.
    - Without these activities, testimony based on forensic casework using the STR kits would not be possible.
    - Each of these activities is either necessary for use of the results of the STR kits in legal proceedings or in the preparation to do so.

Forensic Research

- DNA testing is a two step process, 1) one biochemical and the other 2) statistical.
    - The first step uses principles of molecular biology and chemistry to determine whether two DNA samples have the same or similar genetic profiles.

- The second step uses statistics to estimate the frequency of the occurrence of a profile in different human populations.

- Without that second step, DNA evidence would be inadmissible in legal proceedings.
  - Because different populations have differing frequencies of genetic variations, a DNA profile match has a different statistical significance based on the genetic background of the source of a sample and the relevant population group.
  - The forensic research necessary to determine this statistical significance is referred to as population genetic studies. This also includes building databases from the analysis of samples collected throughout the world using STR kits.
  - These population studies encompass the statistical analysis of the performance of STR kits across a large group of samples from different defined populations (i.e. Caucasian, Japanese, African American, Tamil, etc.). The information provided by population studies is the only basis for testifying regarding the probability of a DNA profile match.

- Forensic research and development is also essential for the first step of providing a DNA profile match.
  - Without research in areas such as DNA collection, DNA extraction, quantifying the amount of DNA present, and understanding limitations of manual and automated procedures, a rigorous basis for explaining a DNA profile match and any anomalies could not be admitted in a court of law.
  - These studies are necessary foundations for testimony in legal proceedings because they establish the reliability, reproducibility, accuracy, and acceptability of a particular methodology as evidence.
  - The forensic community refers to these studies as "Validation."

- As explained in the QAS, Validation is a process by which a procedure is evaluated to determine its efficacy and reliability for forensic casework analysis and includes the following:
  - (A) Developmental validation is the acquisition of test data and determination of conditions and limitations of a new or novel DNA methodology for use on forensic samples; and
  - (B) Internal validation is an accumulation of test data within the laboratory to demonstrate that established methods and procedures perform as expected in the laboratory. QAS ¶ 8.

- The QAS defines Developmental validation studies as research into, characterization of genetic markers, species specificity, sensitivity, stability, reproducibility, testing on case-type samples, population statistics, mixed sample analysis, results precision and accuracy, and evaluating PCR-reaction performance.
  - PCR-based studies include assessing reaction conditions, assessment of differential and preferential amplification, effects of multiplexing, assessment of appropriate controls, and PCR product detection studies.

- Developmental validation must precede the use of any methodology for forensic DNA analysis. In addition, peer-reviewed publication of the underlying scientific principle(s) of a technology is required.
- Without performing Developmental validation, existing DNA forensic kits could not be improved or enhanced and new kits could not be developed. QAS ¶ 8.2.

- Additionally, the QAS defines Internal validation studies as including tests on known and non-probative evidence samples or mock evidence samples, studies of reproducibility and precision, sensitivity and stochastic studies, analyzing mixed samples, and contamination assessment.
  - It also requires an evaluation of all manual and robotic methods used by each laboratory and review and approval by the laboratory's technical leader prior to using a procedure for forensic applications. QAS ¶ 8.3.
  - These studies are required for establishing each laboratories interpretation guidelines which is essential for the analysis of the data obtained in forensic casework.
- All of the above types of Validation studies are performed in preparation for or use in legal proceedings as they encompass determining the acceptability of a particular methodology in a court of law.

Forensic Education

- Forensic testing (casework) is complex and technical work, and as such would not be possible without the proper education in forensic science.
  - Accordingly, a forensic education is necessary as preparation for performing actual forensic testing for use in legal proceedings.
- The Forensic Science Education Programs Accreditation Commission (FEPAC) of the American Academy of Forensic Sciences (AAFS) works to "develop, to implement, to maintain, and to enhance rigorous, consensus educational standards for undergraduate and graduate forensic science programs at accredited institutions of higher education." *See* **FEPAC Accreditation Standards**, ¶ 1.2, a true and correct copy of which is attached hereto as **EXHIBIT 2**.
  - Toward this end, FEPAC has established Accreditation Standards for university programs leading to a degree in forensic science (as set forth in the FEPAC Accreditation Standards).
  - According to FEPAC, degree programs in forensic science "***shall*** be . . . consistent with the goals and objectives of the forensic science community to ***produce a technically skilled and educated workforce***." This is set forth in the FEPAC Accreditation Standards at ¶ 4.1.
  - Thus, a forensic science education is practically oriented; it is foundational to and directly in preparation for, a forensic scientist to perform forensic testing (casework) for use in legal proceedings.

- "[L]aboratory-based instruction" is mandated by FEPAC. This is set forth in the FEPAC Accreditation Standards at ¶ 4.3.1.
    - The laboratory-based instruction includes actual use of STR kits by students and instructors.
    - Such use is consistent with the manner and purpose for which STR kits were designed, *i.e.*, to analyze biological specimens for the identification of individuals by means of their genetic profiles.
    - Without forensic education, there would be no forensic testing for use in legal proceedings. Forensics education is required preparation to qualify a forensic scientist to perform forensic testing and give testimony in legal proceedings.
- The University of North Texas Health Sciences Center has a forensic education and training program accredited by the FEPAC of the AAFS.
    - It is a professional masters' program, *i.e.*, the sole purpose and mission of the program is to educate and train individuals to become forensic DNA analysts who perform actual forensic casework.
    - The program is focused on forensic genetics, and therefore DNA testing using STR kits involving human samples constitutes a substantial part of the curriculum.
        - Students in the program work on mock cases. The only way that this can be done is to use STR kits and techniques used in actual forensic testing for use in legal proceedings.

Forensic Training

- Upon completion of a forensic science education from an accredited degree program, graduates must undergo still further training and testing before they can perform actual forensic testing for use in legal proceedings.
- As discussed above, the Federal Bureau of Investigation has published a set of mandatory standards known as Quality Assurance Standards for Forensic DNA Testing Laboratories.
    - As stated therein, the QAS "describe[s] the quality assurance requirements that laboratories performing forensic DNA testing or utilizing the Combined DNA Index System (CODIS) shall follow to ensure the quality and integrity of the data generated by the laboratory" (emphasis added).
    - In other words, all forensic testing (casework) for use in or preparation for legal proceedings must comply with the FBI's QAS.
- Under the QAS, forensic analysts who perform forensic testing for use in legal proceedings must first be trained according to stringent qualification standards. These include "training requirements for casework analysis" and a "competency test," and furthermore includes ongoing "proficiency testing," as specified in the QAS definition of an "Analyst":

> an employee that has successfully completed the laboratory's ***training requirements for casework sample analysis***, passed a ***competency test***, and has entered into a ***proficiency testing program*** according to these standards. This individual conducts and/or directs the analysis of forensic samples, interprets data, and reaches conclusions.

This is found in the QAS at ¶ 2.

- Both competency testing and proficiency testing require the use of STR kits. Under the QAS, without meeting these training requirements, an Analyst cannot perform forensic testing for use in legal proceedings.
- Forensic training is therefore integral to forensic testing for use in legal proceedings; it is done in preparation for forensic testing for use in legal proceedings.
- The QAS elaborates very specifically on the standards for forensic training of forensic analysts and technicians.
    - Again, these standards are mandatory. As set forth in QAS ¶ 5.1, "Laboratory personnel shall have the education, training and experience commensurate with the examination and testimony provided."
    - Specifically, they mandate hands-on experience with the tools and techniques used in actual forensic testing for use in legal proceedings, including hands-on use of STR kits. For example:

:

- QAS ¶ 5.1.2.1 provides that "***Practical exercises*** shall include the examination of a range of samples routinely encountered in casework." (emphasis added).
- QAS ¶ 5.4.2.1 provides that "the analyst shall complete the analysis of a range of samples routinely encountered in forensic casework prior to independent work using DNA technology."
- QAS ¶ 5.4.2 provides "***Minimum*** experience requirements," including that "the analyst shall have six (6) months of forensic human DNA ***laboratory experience***."
- QAS ¶ 5.1.2.2 provides that "[t]he training program shall teach and assess the ***technical skills*** and knowledge required to perform DNA analysis."
- QAS ¶ 5.1.2.2.1 provides that "[t]he training program shall require an individual's demonstration of competency."
- QAS ¶ 5.1.2.2.3 provides that "[a]ll analyst/technician(s), regardless of previous experience, shall successfully complete a competency test(s)

covering the routine DNA methodologies to be used prior to participating in independent casework analysis."

- QAS ¶ 2 provides that competency testing is required to prove that a forensic analyst or technician "has demonstrated ***achievement of technical skills*** and met minimum standards of knowledge ***necessary to perform forensic DNA analysis***."

- For these reasons, forensic analysts and technicians could not perform forensic testing for use in legal proceedings without first completing rigorous forensic training to acquire the requisite knowledge, technical skills, and hands-on experience.

Summary of Forensics Research, Education &Training

- He would explain that if forensic research, education, and training were not allowed, within a finite period of time (a matter of months) there would be no market for STR kits. For example:
  - New lots of kits could not be validated.
  - Existing forensic scientists could not take the required semi-annual proficiency tests using STR kits, which would disqualify them under the QAS from performing actual forensic casework.
  - New and improved kits and procedures could not be developed, tested, and validated.
- To the extent problems arise with any existing kits, those problems could not be evaluated, tested, and refined. Such problematic kits would open the door to defense challenges at trial, casting doubt on the use and reliability of DNA testing overall.

Experience with AB and Promega STR Kits

- He uses AB and Promega Kits
  - In his and his assistants' hands, AB kits are much better
  - Use Promega kits for paternity because of price
    - Paternity doesn't require the same sensitivity

2006 Cross License:

- If shown §1.6 of the 2006 Cross License, which is the definition of "Forensics and Human Identity Applications," he would be familiar with the terms used in that definition.
  - He uses AB STR kits at the Center for Human Identification
  - About 97% of the uses of the AB STR kits would fit within the definition in §1.6 as he understands that definition?

- He would explain that when a forensic scientist testifies about a "DNA match," that does not mean "this is the person" because the DNA match does not rule out the possibility that someone else might have those same DNA markers.
    - One would need to go further and compare it against the DNA population databases that he discussed earlier in his testimony.
        - Those databases have been built by the FBI and other police laboratories all over the world.
        - There are separate databases for most population groups
        - They are constantly being added to.
        - The way they make the databases is to use STR kits to make a DNA fingerprint of people who are arrested, convicted, or otherwise contribute DNA samples.
    - After the forensic scientist determines there is a match, the next step is to compare it to the relevant database and determine the statistical probability that another person in that population group could have the same DNA markers.
        - And then the scientist can testify that the probability of anyone else in the group having the same DNA markers is less than 1 in 100 billion, for example.
        - Indeed, the forensic testimony would likely not even be admissible unless the comparison to the database was also made.
    - He would state that the population database is absolutely essential to using the STR kits for legal proceedings.
        - The population database would be included in the definition in §1.6 of the 2006 Cross License regarding preparation for use of the results of STR testing in a legal proceeding.
- He would summarize the requirements for validation of the test protocols that he discussed earlier in his testimony.
    - He would consider that to be part of forensic research and with the definition of §1.6 of the 2006 Cross License.
    - A forensic scientist would not be able or allowed to testify in any case if the validations had not been done.
- He would summarize the training that is required before a forensic scientist can testify in any case, as he discussed earlier in his testimony.
    - When they are training with the kits, they are attempting to identify individuals.
    - A forensic scientist would not be able or allowed to testify in any case without this preparation or training.
    - He understands forensic training to fall within the definition in §1.6 of the 2006 Cross License.

- He would testify that other than forensics and paternity, there are other uses that scientists and health care professionals have developed for STR kits.
    - For example, he would testify that cell line identification/authentication, bone marrow transplant monitoring, and fetal cell analysis (amniocentesis) would be other uses to which scientists and health care professionals put STR kits
    - He would explain that these uses fall within his understanding of the language in §1.6 of the 2006 Cross License.

American Academy of Forensic Sciences

Forensic Science Education Programs Accreditation Commission (FEPAC)

ACCREDITATION STANDARDS

Adopted by FEPAC – May 16, 2003
Approved by the AAFS Board of Directors – August 9, 2003
Revised by FEPAC – July 22, 2011

FORENSIC SCIENCE EDUCATION PROGRAMS ACCREDITATION COMMISSION

ACCREDITATION STANDARDS

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FORENSIC SCIENCE EDUCATION PROGRAMS ACCREDITATION COMMISSION

ACCREDITATION STANDARDS

1.0 INTRODUCTION

1.1 Mission

The mission of the Forensic Science Education Programs Accreditation Commission (FEPAC) is to maintain and enhance the quality of forensic science education through a formal evaluation and accreditation system for college-level academic programs that lead to a baccalaureate or graduate degree.

1.2 Purpose

The purposes of FEPAC are:

- To use the National Institute of Justice Technical Working Group for Education and Training in Forensic Science (TWGED) and the TWGED-DE curriculum guidelines to develop, to implement, to maintain, and to enhance rigorous, consensus educational standards for undergraduate and graduate forensic science programs at accredited institutions of higher education;
- To develop and to implement a set of well-defined procedures for evaluating forensic science programs against those standards; and,
- To encourage self-evaluation and continual improvement of forensic science education programs through the accreditation process.

1.3 History

The American Academy of Forensic Sciences (AAFS) was established in 1948 to promote education for and research in the forensic sciences; to encourage the study, improve the practice, elevate the standards, and advance the cause of the forensic sciences; to promote interdisciplinary communications; and to plan, organize, and administer meetings, reports, and other projects for the stimulation and advancement of these and related purposes.

An assessment of forensic sciences published in 1999 by the National Institute of Justice (NIJ), entitled "Forensic Science: Review of Status and Needs," described the educational and training needs of the forensic science community as "immense." Among the recommendations contained in the report was the establishment of the following:

- National standards for education in forensic sciences;
- An independent, community-wide, consensus-building, standard-setting body such as a technical working group for education in forensic sciences; and
- An accreditation system for forensic science education programs.

The NIJ established a technical working group for education and training in forensic sciences (TWGED) in 2001 for the purpose of recommending sample curricular guidelines for educational programs in forensic sciences. The results of TWGED's deliberations were delineated in a research report published in 2003, entitled "Education and Training in Forensic Sciences: A Guide for Forensic Science Laboratories, Educational Institutions, and Students."

Acknowledging the importance of an accreditation system for academic programs built on the foundation of TWGED, the AAFS in 2002 established an *ad hoc* committee, called Forensic Education Program Accreditation Committee, to explore issues related to the development of such an accreditation system. In 2004, the Forensic Science Education Programs Accreditation Commission became an official standing committee of the AAFS and awarded its first accreditation in February 2004.

A second NIJ technical working group on education and training for digital evidence published its reports in 2007. In 2009 a committee composed of four FEPAC Commissioners and four representatives from academic and practitioner digital evidence programs began the process of incorporating standards for digital evidence forensic science programs into the FEPAC Standards.

1.4 Scope of Accreditation

- FEPAC accredits forensic science education programs that lead to a bachelor's or master's degree in forensic science or in a natural or computer science with a forensic science concentration.
- An eligible forensic science program must be located in a regionally accredited institution of higher education that requires state, province, or equivalent approval.
- Forensic Science programs outside the United States are also eligible if they do not have an established forensic science education accreditation system in their jurisdiction.

FEPAC promotes academic quality through formal accreditation of forensic science programs in the United States. All programs that FEPAC accredits are located within institutions that are accredited by a regional accreditation organization. The FEPAC accreditation process and policies employ rigorous, consensus standards that assure and advance academic quality at accredited institutions.

To ensure the accreditation requirements are valid and relevant indicators of the quality of education, FEPAC reviews its Accreditation Standards and Policies & Procedures on a regular schedule. In addition, FEPAC commissioners and on-site evaluators are trained on the various aspects of the accreditation process as a measure to promote reliability in application of the standards. Education programs are also monitored through annual reports to ensure continuous compliance with quality measures.

2.0 OVERVIEW OF THE STANDARDS

FEPAC accreditation standards guide and inform all aspects of the FEPAC accreditation program. The standards are divided into three parts: general standards that all programs must meet, undergraduate program standards, and graduate program standards.

3.0 GENERAL STANDARDS FOR ALL PROGRAMS

3.1 Eligibility

To be eligible for FEPAC accreditation or re-accreditation, a forensic science program shall document that:

1. The institution offering the program is regionally accredited, and,
2. The degree awarded upon successful completion of the program is at least a bachelor's degree in one of the following:
    - Forensic Science
    - Digital Forensics
    - A degree in one of the following disciplines with a concentration in forensic science or digital forensics:
        - Computer Science
        - Computer/Electrical Engineering
        - Information Systems

- Information Technology
- A natural science

3. A program seeking FEPAC accreditation shall have graduated at least two classes before the Application for Accreditation (FEPAC Form 5.1) is submitted.

3.2 Planning and Evaluation

The program shall have an explicit process for evaluating and monitoring its overall efforts to fulfill its mission, goals, and objectives; for assessing its effectiveness in serving its various constituencies; for modifying the curriculum as necessary, based on the results of its evaluation activities; and for planning to achieve its mission in the future. Toward this end, the program shall conduct at regular intervals an analytical self-evaluation that responds to the FEPAC standards and includes a summary statement both of the program's strengths and weaknesses with regard to each standard and of the program's performance with respect to student achievement. The program evaluation system shall include at least the following elements:

1. An analysis of the results of the student's performance in a capstone experience; e.g., an evaluation of forensic science standardized test results, publications and/or reports;
2. Exit questionnaire and interview of graduates;
3. Post-graduate assessment, such as job placement surveys; and
4. The program must demonstrate how collected information is used in the evaluation and development of the program to meets its stated mission, goals, and objectives.

3.3 Institutional Support

The program shall receive adequate support from the institution. As with other natural or computer science programs, the financial resources available to the program shall be sufficient to allow the program to achieve its mission, goals, and objectives. Classrooms, laboratories, and other program facilities, including equipment and supplies, shall be adequate for the size and scope of the program. Instructional and support services for the program shall also be adequate.

3.4 Faculty

The faculty shall be able to fully support the program's mission, goals, and objectives. Specifically, faculty members and other instructional personnel shall be appropriately qualified, by education and experience, and adequate in number to implement the instructional program. In addition, the number of faculty members shall be sufficient to ensure the offering, on a regular basis, of the full range of courses needed for the degree program. Over reliance on part-time or adjunct faculty members may be deemed inadequate institutional support.

At least 50 percent of the full-time science faculty teaching in the forensic science program shall have an appropriate doctoral degree. Faculty members with working experience in a forensic science laboratory are preferred. Forensic science faculty includes any faculty member who teaches a forensic science course or a support course designed specifically for the program. The scientific and educational capabilities of the faculty should be distributed over the major areas of the program. In addition to the general qualifications specified above, graduate faculty are expected to have demonstrated research activity appropriate to their institution's mission.

Full-time faculty members shall oversee all coursework and ensure its applicability to the program's mission, goals, and objectives.

The program shall have well-defined policies and procedures to recruit, appoint, and promote qualified faculty, to evaluate the competence and performance of faculty, and to support the professional development and advancement of faculty.

3.5 Student Support Services

The program shall provide adequate student support services including mentoring, academic advising, and career and placement services. The program shall also provide an environment and culture that are congruent with professional standards and behaviors.

3.6 Recruiting and Admissions Practices, Academic Calendars, Catalogs, Publications, Grading, and Advertising

The program shall have policies and procedures for student recruitment and admissions that locate and select qualified individuals who have the educational prerequisites and the interest and motivation to pursue careers in forensic science. These policies and procedures shall identify the scientific background necessary and clearly define the expectations for admission to, continuation in, and completion of the program. All statements made about the program in any promotional advertising, catalogs, or other institutional publications shall be accurate. In addition, the student shall be advised of the typical suitability requirements particular to employment in the field. Specifically, students should be advised that background checks similar to those required for law enforcement officers are likely to be a condition of employment (Reference: NIJ Report NCJ 203099 – "Qualifications for a Career in Forensic Science," pp.7-10).

If pursuing a career as a forensic DNA analyst, nine cumulative hours of course work in biochemistry, molecular biology, and genetics is required; course work in population genetics is desirable. Employers will require documentation, such as a syllabus, for course work with other titles.

The program shall ensure that all students receive timely and accurate information about the academic calendar, required coursework and degree requirements, grading policies and satisfactory academic progress, and other relevant academic policies.

All application, admission, and degree-granting requirements and regulations shall be applied equitably to individual applicants and students regardless of age, sex, race, disability, religion, or national origin.

3.7 Record of Student Complaints

The program shall have a procedure for handling student complaints. At a minimum, this procedure shall include informing students of their right to file a complaint with the college or university and providing students with the institution's procedures for filing such a complaint.

The program shall maintain a record of all complaints it receives, as well as the resolution of those complaints. The program shall make this record available to members of the on-site evaluation team during the on-site visit.

3.8 Distance Learning and Other Alternative Delivery Mechanisms

FEPAC considers distance learning to be one of several acceptable forms of instructional methodology. Therefore, FEPAC does not maintain separate standards for distance learning or other alternative delivery mechanisms and expects all programs to meet the same standards for accreditation, regardless of the instructional methodology used.

FEPAC acknowledges that laboratory-based instruction is integral to any science-based discipline such as forensic science. Therefore, any program that offers at least some instruction via distance learning shall demonstrate that it includes an appropriate laboratory experience for all students.

3.9 Success with Respect to Student Achievement

The program shall demonstrate that its graduates have a basic foundation in the scientific and laboratory problem-solving skills necessary for success in a modern crime laboratory. The program may do this through the use of a formal, objective tool, such as the Forensic Science Assessment Test from the American Board of

Criminalistics, or through other appropriate pre-graduation assessment measurements.

The program shall also document its record of student performance, as measured by post-graduate assessments, and any additional outcome measures the program may use to assess student progress and achievement. These records shall be maintained for at least five years after student graduation.

At least one measure of student achievement must be listed on the program's website. The measure(s) to be placed on the website are determined by the institution or program and should be updated annually. The measures of student performance listed on the program's website must also be listed on the annual report to FEPAC.

3.10 Professional Involvement

The program shall provide service to the forensic science profession and to the community through some combination of communication, collaboration, consultation, technical assistance, continuing education programs, and any other means it may have for sharing the program's professional knowledge and competence. The purpose of this involvement is to provide opportunities for faculty and students to contribute to the advancement of the field of forensic science, and to maintain program currency and credibility with practitioners and forensic science laboratory administrators.

3.10a Interaction with Forensic Science Laboratories

The program shall demonstrate formal, regular interaction with at least one operational forensic science laboratory. This interaction must be on-going and documented. This relationship must take the form of two or more of the following:

1. Student internships;
2. Training opportunities where the program provides instruction to laboratory personnel;
3. Faculty serving on laboratory advisory committees;
4. Coordinated research initiatives between the laboratory and academic program;
5. Professional activities coordinated between the laboratory and the academic program;
6. Laboratory personnel serving in an advisory capacity to the academic program.

3.10b Interaction with Forensic Science Organizations

The program shall demonstrate formal, regular interaction with at least one professional forensic science organization.

4.0 UNDERGRADUATE PROGRAM STANDARDS

An undergraduate forensic science program shall provide a basic foundation in the scientific and laboratory problem-solving skills necessary for success in a modern forensic laboratory. Such a program shall combine rigorous scientific and laboratory training with exposure to the breadth of forensic science disciplines, including forensic science practice, law enforcement, and ethics.

4.1 Mission, Goals, and Objectives

The undergraduate forensic science program shall have a clearly formulated mission with well-defined supporting goals and educational objectives. The mission statement should be a clear and succinct representation of the program's purpose for existence, its philosophies, goals, and ambitions. The mission shall be appropriate to the institution and consistent with the goals and objectives of the forensic science community to produce a technically skilled and educated workforce. The goals and objectives shall be clearly specified, consistent with the mission, and appropriate in light of the degree(s) awarded.

The undergraduate forensic science degree should not necessarily be viewed as a terminal degree but as a preparation for a variety of graduate and professional degrees including clinical and analytical chemistry,

medicine, law, and biomedical research and advanced degrees in forensic science.

4.2 Undergraduate Admission Requirements

At a minimum, a high school diploma or GED shall be required for admission into a forensic science undergraduate program. Additionally, a program shall be in place to assist and advise entering students to ensure that they have the requisite background in science and mathematics for success in the degree.

4.3 Curriculum

For general forensic science programs with emphasis in chemistry, biology, or toxicology, standards 4.3.1a through 4.3.1d should be followed. For forensic science programs with an emphasis on digital evidence, standards 4.3.2a through 4.3.2d should be followed.

No course may be used to satisfy more than one of the standards in 4.3.1a-d or 4.3.2a-d.

4.3.1 General Curriculum

The undergraduate program in forensic science shall offer a coherent curriculum that reflects the mission and goals of the program and provides the student with the appropriate skills requisite for the bachelor's degree.

The curriculum shall, at a minimum, ensure that each student:

1. Obtain a thorough grounding in the natural or computer sciences;
2. Build upon this background by taking a series of more advanced science classes; and
3. Develop an appreciation of issues specific to forensic science through course work and laboratory-based instruction.

The following topics must be covered in the curriculum:

- Courtroom testimony
- Introduction to law
- Quality assurance
- Ethics
- Professional practice
- Evidence identification, collection, processing
- Survey of forensic science

Normally, a topic will involve multiple class meetings and may involve multiple learning modalities, such as lectures, laboratories, and demonstrations. Evaluation of student mastery of each topic may be done through a number of modalities, but the topic material must be specifically addressed in a syllabus and assessed.

The program shall have clear procedures for assessing and documenting each student's progress toward fulfillment of these objectives.

4.3.1a-d Specific Curricular Requirements

The specific curricular requirements that follow are based on the fact that most forensic scientists work in areas such as drug analysis, trace analysis, firearms and toolmarks, and forensic biology. Students seeking to work in alternative areas of forensic science, such as computer analysis, latent print recovery and comparison, or crime scene reconstruction, will require other curricula or further training.

Because certain forensic science disciplines require more rigorous coursework than the minimum described below, in particular, more biology and chemistry, the program shall ensure that its curriculum is adequate to prepare students for specialization in subdisciplines of forensic science such as forensic biology, forensic chemistry, toxicology, or pattern evidence examination.

4.3.1a Natural Science Core Courses

Biology: at least one course, which includes an associated laboratory, in biology for science majors (4 semester hours).

Physics: at least two courses, each of which includes an associated laboratory, in physics for science majors (8 semester hours). Note: Calculus-based physics is preferred but not required.

Chemistry: at least four courses, each of which includes an associated laboratory. Two of the courses shall be in general chemistry for science majors (8 semester hours), and two shall be in organic chemistry for science majors (8 semester hours).

Mathematics: at least one course in differential and integral calculus (3 semester hours) and at least one course in statistics (3 semester hours).

4.3.1b Specialized Science Courses

A minimum of 12 additional semester hours in more advanced coursework in chemistry or biology. Note: These classes shall be consistent with the degree program and shall meet the needs of students specializing in sub disciplines of forensic science. At least two of the classes shall include laboratory training.

Examples of specialized science courses include

- Biochemistry
- Molecular biology
- Genetics
- Population genetics
- Inorganic chemistry
- Analytical/quantitative chemistry
- Physical chemistry
- Instrumental analysis
- Cell biology
- Pharmacology
- Calculus II
- Microbiology

4.3.1c Forensic Science Courses

A minimum of 15 semester hours in forensic science coursework must be covered in the curriculum.

Of these 15 hours, 9 semester hours shall involve classes in forensic chemistry, forensic biology, physical methods, or microscopy and contain a laboratory component. Forensic science internships or independent study/research may not be used to fulfill the 9 semester hours containing the laboratory component.

4.3.1d Additional Courses

A minimum of 19 additional semester hours of advanced, upper level courses that provide greater depth in the student's area of specialization beyond an introductory level in the program are required. Students can use these additional courses to begin to specialize along a forensic science discipline track.

4.3.2 General Baccalaureate Curriculum Requirements for Digital Evidence Programs

The specific curricular requirements that follow are based on the fact that most digital forensic scientists work in areas such as electronic discovery, criminal investigation, litigation support, information security, incident response, and policy compliance. Students seeking work in alternative areas of forensic science such as drug analysis, trace analysis, firearms and toolmarks, forensic biology, or crime scene reconstruction will require other curricula or further training.

Because certain digital forensic science disciplines require more rigorous coursework than the minimum described below, particularly more computer science, mathematics and networking, the program shall ensure

that its curriculum is adequate to prepare students for specialization in sub-disciplines of digital forensic science such as network forensics, audio and video forensics, mobile device forensics, anti-forensics, or malware analysis.

In addition, the curriculum must cover the following topics related to forensic science:

- Courtroom testimony
- Introduction to law
- Quality assurance
- Ethics
- Professional practice
- Evidence identification, collection, processing
- Survey of forensic science

Normally, a topic will involve multiple class meetings and may involve multiple learning modalities, such as lectures, laboratories, and demonstrations. Evaluation of student mastery of each topic may be done through a number of modalities, but the topic material must be specifically addressed in a syllabus and assessed.

4.3.2a Computing and Information Science and Technology Core Courses

A minimum of 24 semester hours of coursework shall include the following topics:

- Computer organization and architecture
- File systems and operating systems
- Computer networking
- Information, computer, network or enterprise security
- Programming theory and languages
- Statistics
- Data structures/database design
- Web or mobile application design and development
- Technical writing

4.3.2b Specialized Digital Forensic Science Courses

A minimum of 24 semester hours is required in digital forensic science course work that covers the following topics: identification, acquisition, authentication, examination, analysis, and reporting. Courses in computer forensics, network forensics and a capstone experience are required.

Internships or independent study/research courses may be used to fulfill up to three hours of this requirement.

4.3.2c Forensic Science Courses

A minimum of 15 additional semester hours is required in courses that provide greater depth in the student's area of specialization.

4.3.2d Additional Courses

A minimum of 15 additional semester hours of advanced, upper level courses that provide greater depth in the student's area of specialization beyond an introductory level in the program are required. Additional semester hours to complete the minimum of 120 semester hours are to be defined by the individual institution.

4.4 Program Director

The program director shall be a full-time faculty member at the academic institution, appropriately qualified to meet the program's stated mission, goals, and objectives, and to provide leadership in forensic science education, research, and other scholarly activities so that students are adequately prepared for forensic science practice. The program director shall meet the following requirements:

1. Minimum of a Master's or professional degree appropriate for a forensic science program, and at least three years relevant experience as a forensic-science practitioner in an operational forensic science laboratory setting (the three years not including any training period); OR earned doctorate in an appropriate discipline, and three years experience as an academic forensic scientist that includes appropriate educational, research and service contributions to forensic science
2. Documented management experience appropriate to the duties assigned to the position.

5.0 Graduate Program Standards

A graduate forensic science program shall provide advanced education in the scientific and laboratory problem-solving skills necessary for success in a modern forensic laboratory. Such a program shall combine rigorous scientific and laboratory training with exposure to the breadth of forensic science disciplines, including forensic science practice, law enforcement, and ethics.

5.1 Mission, Goals, and Objectives

The graduate forensic science program shall have a clearly formulated mission appropriate to the institution and shall include teaching and learning, research, and service. The mission statement should be a clear and succinct representation of the program's purpose for existence, its philosophies, goals, and ambitions. The mission shall be appropriate to the institution and consistent with the goals and objectives of the forensic science community to produce a technically skilled and educated workforce. The goals and objectives shall be clearly specified, consistent with the mission, and appropriate in light of the degree(s) awarded.

5.2 Graduate Admission Requirements

A bachelor's degree in a forensic or natural science, computer science, computer electronic or electrical engineering, information systems or information technology (or its equivalent coursework in a relevant field) shall be required for entrance into the appropriate graduate forensic science program. Undergraduate work should be evaluated to determine if the applicant has sufficient scientific or technical background to successfully complete the graduate program.

5.3 Curriculum

The graduate program in forensic science shall offer a coherent curriculum that reflects the mission and goals of the program.

5.3.1 General Curricular Requirements

The curriculum shall, at a minimum, ensure that each student:

1. Develop an understanding of the areas of knowledge that are essential to forensic science;
2. Acquire skills and experience in the application of basic forensic science concepts and of specialty knowledge to problem solving;
3. Be oriented in professional values, concepts and ethics; and
4. Demonstrate integration of knowledge and skills through a capstone experience, such as a formal, objective tool, (e.g., the American Board of Criminalistics Forensic Science Aptitude Test), or other comprehensive examination, thesis, and/or research projects.

The program shall define clear learning objectives for each discrete component of the curriculum. The program shall have clear procedures for assessing and documenting each student's progress toward the fulfillment of these learning objectives and toward readiness for forensic science practice.

The program shall provide students with the basic knowledge necessary for effective testimony as an expert witness, and each student shall participate in practical experiences where they will render expert testimony, e.g., moot court.

For general forensic science programs with emphasis in chemistry, biology, or toxicology, standards 5.3.1a-d should be followed. For forensic science programs with an emphasis on digital evidence, standards 5.3.2a-d should be followed.

5.3.1a-d Specific Topic Requirements within the Curriculum

The curriculum shall include the topics described in standards 5.3.1a-d for traditional forensic science programs.

5.3.1a Core Forensic Science Topics

The following topics must be part of the curriculum:

- Crime scene investigation
- Physical evidence concepts
- Law/science interface
- Ethics and professional responsibilities
- Quality assurance
- Analytical chemistry and instrumental methods of analysis
- Drug chemistry/toxicology
- Microscopy and materials analysis
- Forensic biology
- Pattern evidence

The emphasis on each topic should be appropriate in light of the degrees awarded. However, a minimum of 10 instructional hours must be spent on each topic.

Normally, a topic will involve multiple class meetings and may involve multiple learning modalities, such as lectures, laboratories, and demonstrations. Evaluation of student mastery of each topic may be done through a number of modalities, but the topic material must be specifically addressed in a syllabus and assessed.

5.3.1b Courses in Specialized Areas

The curriculum must include graduate-level science courses appropriate to the specialization, track(s) and/or concentration(s) offered by that institution. For example, courses covering the topics of molecular biology and population genetics, advanced analytical chemistry, toxicology, and materials analysis may be appropriate.

5.3.1c Graduate Seminar

A formal seminar, which is a requirement of a course, presented by invited experts, faculty, and/or students covering topics such as published work, original research, and other relevant topics must be offered.

5.3.1d Research

Each student is required to complete an independent research project. The research project shall culminate in a thesis or written report of publishable quality. The academic program must have written guidelines for the format of the thesis/report and for the evaluation of the oral presentation.

Each student is required to have a committee of at least three individuals who are responsible for mentoring the project. One member of the student's research committee must be a full-time faculty member of the program. The other two members can include full or part-time faculty, forensic practitioners and others with specialized knowledge. At least one member of the committee must be external to the department sponsoring the research. In addition, each student must present the results of the work orally, in a public forum, before the committee. Presentations at professional meetings do not meet this requirement.

The research shall be conducted in an environment conducive to research and scholarly inquiry, and shall provide the opportunity for faculty and students to contribute to the knowledge base of forensic science, including research directed at improving the practice of forensic science.

5.3.2a-d Specific Topic Requirements within the Curriculum for Digital Evidence Programs

The curriculum shall include the topics described in standards 5.3.2a through 5.3.2d.

5.3.2a Core Forensic Science Topics

The following topics must be part of the curriculum:

- Crime scene investigation
- Physical evidence concepts
- Law/science evidence
- Ethics and professional responsibilities
- Quality assurance
- Forensic biology
- Pattern evidence
- Hardware forensic concepts
- Software forensic concepts
- Network forensic concepts

5.3.2b Courses in Specialized Areas

The curriculum must include graduate-level science courses appropriate to the specialization, track(s), and or concentration(s) offered by that institution (e.g., network forensics, personal electronic device (PED) forensics, embedded device forensics, incident response, reverse engineering, multimedia forensics, legal issues, information security, operational management). An advanced computer and network forensics course that requires a graduate course as prerequisite must be completed.

5.3.2c Graduate Seminar

A formal seminar, which is a requirement of a course, presented by invited experts, faculty, and/or students covering topics such as published work, original research, and other relevant topics must be offered.

5.3.2d Research

Each student is required to have a committee of at least three individuals who are responsible for mentoring the project. One member of the student's research committee must be a full-time faculty member of the program. The other two members can include full or part-time faculty, forensic practitioners and others with specialized knowledge. At least one member of the committee must be external to the department sponsoring the research. In addition, each student must present the results of the work orally, in a public forum, before the committee. Presentations at professional meetings do not meet this requirement.

The research shall be conducted in an environment conducive to research and scholarly inquiry, and shall provide the opportunity for faculty and students to contribute to the knowledge base of forensic science, including research directed at improving the practice of forensic science.

5.4 Program Director

The program director shall be a full-time faculty member at the academic institution appropriately qualified by academic experience, research qualifications, and background in program administration to meet the program's stated mission, goals, and objectives, and to provide leadership in forensic science education, research, and other scholarly activities so that students are adequately prepared for forensic science practice. The program director shall meet the following requirements:

1. Minimum of an earned Doctorate degree appropriate for a forensic science program, AND at least five years relevant experience as an academic forensic scientist that includes appropriate educational, research and service contributions to forensic science; OR at least five years relevant experience as a forensic-science practitioner, not including any training time in an operational forensic science laboratory setting
2. Documented research experience in a forensic science discipline or in methods and techniques adapted, validated and implemented by the forensic science community,
3. Documented management experience appropriate to the duties assigned to the position.

QUALITY ASSURANCE STANDARDS FOR FORENSIC DNA TESTING LABORATORIES

This document consists of definitions and standards. The standards are quality assurance measures that place specific requirements on the laboratory. Equivalent measures not outlined in this document may also meet the standard if determined sufficient through an accreditation process.

EFFECTIVE DATE:

These standards shall take effect July 1, 2009.

REFERENCES: Federal Bureau of Investigation, "Quality Assurance Standards for Forensic DNA Testing Laboratories" and "Quality Assurance Standards for Convicted Offender DNA Databasing Laboratories," Forensic Science Communications, July 2000, Volume 2, Number 3.

1. SCOPE

The standards describe the quality assurance requirements that laboratories performing forensic DNA testing or utilizing the Combined DNA Index System (CODIS) shall follow to ensure the quality and integrity of the data generated by the laboratory. These standards also apply to vendor laboratories that perform forensic DNA testing in accordance with Standard 17. These standards do not preclude the participation of a laboratory, by itself or in collaboration with others, in research and development, on procedures that have not yet been validated.

2. DEFINITIONS

As used in these standards, the following terms shall have the meanings specified:

Accredited laboratory is a DNA laboratory that has received formal recognition that it meets or exceeds a list of standards, including the FBI Director's Quality Assurance Standards, to perform specific tests, by a nonprofit professional association of persons actively involved in forensic science that is nationally recognized within the forensic community in accordance with the provisions of the Federal DNA Identification Act (42 U.S.C. § 14132) or subsequent laws.

Accuracy is the degree of conformity of a measured quantity to its actual (true) value.

Administrative review is an evaluation of the report and supporting documentation for consistency with laboratory policies and for editorial correctness.

Analyst (or equivalent role, position, or title as designated by the Laboratory Director) is an employee that has successfully completed the laboratory's training requirements for casework sample analysis, passed a competency test, and has entered into a proficiency testing program according to these Standards. This individual conducts and/or directs the analysis of forensic samples interprets data and reaches conclusions.

Analytical documentation is the documentation of procedures, standards, controls and instruments used, observations made, results of tests performed, charts, graphs, photos and other documentation generated which are used to support the analyst's conclusions.

Analytical procedure is an orderly step-by-step process designed to ensure operational uniformity and to minimize analytical drift.

Annual is once per calendar year.

Audit is an inspection used to evaluate, confirm, or verify activity related to quality.

Biochemistry is the study of the nature of biologically important molecules in living systems, DNA replication and protein synthesis, and the quantitative and qualitative aspects of cellular metabolism.

Calibration is the set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material, and the corresponding known values of a measurement.

Casework CODIS Administrator (or equivalent role, position, or title as designated by the Laboratory Director) is an employee of the laboratory responsible for administration and security of the laboratory's CODIS at a laboratory performing DNA analysis on forensic and casework reference samples.

Casework reference sample is biological material obtained from a known individual and collected for purposes of comparison to forensic samples.

CODIS is the Combined DNA Index System administered by the FBI. CODIS links DNA evidence obtained from crime scenes, thereby identifying serial criminals. CODIS also compares crime scene evidence to DNA profiles from offenders, thereby providing investigators with the identity of the putative perpetrator. In addition, CODIS contains profiles from missing persons, unidentified human remains and relatives of missing persons. There are three levels of CODIS: the Local DNA Index System (LDIS), used by individual laboratories; the State DNA Index System (SDIS), used at the state level to serve as a state's DNA database containing DNA profiles from LDIS laboratories; and the National DNA Index System (NDIS), managed by the FBI as the nation's DNA database containing all DNA profiles uploaded by participating states.

Competency test(s) is a written, oral and/or practical test or series of tests, designed to establish that an individual has demonstrated achievement of technical skills and met minimum standards of knowledge necessary to perform forensic DNA analysis.

Competency is the demonstration of technical skills and knowledge necessary to perform forensic DNA analysis successfully.

Contamination is the unintentional introduction of exogenous DNA into a DNA sample or PCR reaction.

Continuing education is an educational activity (such as a class, lecture series, conference, seminar, or short course) that is offered by a recognized organization or individual that brings participants up to date in their relevant area of knowledge.

Coursework is an academic class officially recognized and taught through a college or university program in which the participating student successfully completed and received one or more credit hours for the class.

Critical equipment or instruments are those requiring calibration or a performance check prior to use and periodically thereafter.

Critical reagents are determined by empirical studies or routine practice to require testing on established samples before use on evidentiary or casework reference samples.

Developmental validation is the acquisition of test data and determination of conditions and limitations of a new or novel DNA methodology for use on forensic and/or casework reference samples.

Differential amplification is the selection of one target region or locus over another during the polymerase chain reaction. Differential amplification can also arise between two alleles within a single locus if one of the alleles has a mutation within a PCR primer binding site causing this allele to be copied less efficiently because of the primer-template mismatch.

DNA record is a database record that includes the DNA profile as well as data required to manage and operate NDIS, i.e., the Originating Agency Identifier which serves to identify the submitting agency; the Specimen Identification Number; and DNA personnel associated with the DNA profile analyses.

DNA type **(also known as a DNA profile)** is the genetic constitution of an individual at defined locations (also known as loci) in the DNA. A DNA type derived from nuclear DNA typically consists of one or two alleles at several loci (e.g., short tandem repeat loci). The DNA type derived from mitochondrial DNA is described in relation to the revised Cambridge Reference Sequence (Nature Genetics 1999, 23, 147).

Employee is a person: (1) in the service of the applicable federal, state or local government, subject to the terms, conditions and rules of federal/state/local employment and eligible for the federal/state/local benefits of service; or (2) formerly in the service of a federal, state, or local government who returns to service in the agency on a part time or temporary basis. For purposes of a vendor laboratory, an employee is a person in the service of a vendor laboratory and subject to the applicable terms, conditions and rules of employment of the vendor laboratory.

FBI is the Federal Bureau of Investigation, the Federal agency authorized by the DNA Identification Act of 1994 to issue quality assurance standards governing forensic DNA testing laboratories and to establish and administer the National DNA Index System (NDIS).

Forensic DNA analysis is the process of identification and evaluation of biological evidence in criminal matters using DNA technologies.

Forensic sample is a biological sample originating from and associated with a crime scene. For example, a sample associated with a crime scene may include a sample that has been carried away from the crime scene.

Genetics is the study of inherited traits, genotype/phenotype relationships, and population/species differences in allele and genotype frequencies.

Guidelines are a set of general principles used to provide direction and parameters for decision making.

Integral component is that portion of an academic course that is so significant and necessary to the understanding of the subject matter as a whole, that the course would be considered incomplete without it.

Internal validation is the accumulation of test data within the laboratory to demonstrate that established methods and procedures perform as expected in the laboratory.

Known samples are biological material whose identity or type is established.

Laboratory is a facility: (1) employing at least two full time employees who are qualified DNA analysts; and (2) having and maintaining the capability to perform the DNA analysis of forensic and/or casework reference samples at that facility.

Laboratory support personnel (or equivalent role, position, or title as designated by the laboratory director) are employee(s) who perform laboratory duties exclusive of analytical techniques on forensic or database samples.

Methodology is used to describe the analytical processes and procedures used to support a DNA typing technology: for example, extraction methods (manual vs. automated),

quantitation methods (slot blot, fluorometry, real time), typing test kit and platform (capillary electrophoresis, real-time gel and end-point gel systems).

Molecular biology is the study of the theories, methods, and techniques used in the study and analysis of gene structure, organization, and function.

Multi-laboratory system is used to describe an organization that has more than one laboratory performing forensic DNA analysis.

Multiplex system is a test providing for simultaneous amplification of multiple loci that is either prepared commercially or by a laboratory.

Negative amplification control is used to detect DNA contamination of the amplification reagents. This control consists of only amplification reagents without the addition of template DNA.

NIST is the National Institute of Standards and Technology.

On-site visit is a scheduled or unscheduled visit by one or more representatives of the outsourcing laboratory to the vendor laboratory work site to assess and document the vendor laboratory's ability to perform analysis on outsourced casework.

Outsourcing is the utilization of a vendor laboratory to provide DNA services in which the NDIS participating laboratory takes or retains ownership of the DNA data for entry into CODIS, when applicable. Outsourcing does not require the existence of a contractual agreement or the exchange of funds.

Ownership occurs when any of the following criteria are applicable:

(1) the originating laboratory will use any samples, extracts or any materials from the vendor laboratory for the purposes of forensic testing (i.e. a vendor laboratory prepares an extract that will be analyzed by the originating laboratory);
(2) the originating laboratory will interpret the data generated by the vendor laboratory;
(3) the originating laboratory will issue a report on the results of the analysis; or
(4) the originating laboratory will enter or search a DNA profile in CODIS from data generated by the vendor laboratory.

Performance check is a quality assurance measure to assess the functionality of laboratory instruments and equipment that affect the accuracy and/or validity of forensic sample analysis.

Platform is the type of analytical system utilized to generate DNA profiles such as capillary electrophoresis, real-time gel, and end-point gel instruments or systems.

Polymerase Chain Reaction (PCR) is an enzymatic process by which a specific region of DNA is replicated during repetitive cycles which consist of the following:

(1) denaturation of the template;
(2) annealing of primers to complementary sequences at an empirically determined temperature; and
(3) extension of the bound primers by a DNA polymerase.

Positive amplification control is an analytical control sample that is used to determine if the PCR performed properly. This control consists of the amplification reagents and a known DNA sample.

Precision characterizes the degree of mutual agreement among a series of individual measurements, values, and/or results.

Preferential amplification is the unequal sampling of the two alleles present in a heterozygous locus primarily due to stochastic (random) fluctuation arising when only a few DNA molecules are used to initiate the polymerase chain reaction.

Procedure (protocol, SOP or other equivalent) is an established practice to be followed in performing a specified task or under specific circumstances.

Proficiency testing is a quality assurance measure used to monitor performance and identify areas in which improvement may be needed. Proficiency tests may be classified as:

(1) An internal proficiency test, which is produced by the agency undergoing the test.
(2) An external proficiency test, which may be open or blind, is a test obtained from an approved proficiency test provider.

Qualified auditor is a current or previously qualified DNA analyst who has successfully completed the FBI DNA Auditor's training course.

Quality system is the organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

Quantitative PCR is a method of determining the concentration of DNA in a sample by use of the polymerase chain reaction.

Reagent blank control is an analytical control sample that contains no template DNA and is used to monitor contamination from extraction to final fragment or sequence analysis. This control is treated the same as, and parallel to, the forensic and or casework reference samples being analyzed.

Reference material (certified or standard) is a material for which values are certified by a technically valid procedure and accompanied by, or traceable to, a certificate or other documentation which is issued by a certifying body.

Reproducibility is the ability to obtain the same result when the test or experiment is repeated.

Review is an evaluation of documentation to check for consistency, accuracy, and completeness.

Second agency is an entity or organization external to and independent of the laboratory.

Semi-annual is used to describe an event that takes place two times during one calendar year, with the first event taking place in the first six months of that year and the second event taking place in the second six months of that year and where the interval between the two events is at least four months and not more than eight months.

Service is the performance of those adjustments or procedures specified which are to be performed by the user, manufacturer or other service personnel in order to ensure the intended performance of instruments and equipment.

Technical Leader (or equivalent role, position, or title as designated by the laboratory director) is an employee who is accountable for the technical operations of the laboratory and who is authorized to stop or suspend laboratory operations.

Technical review is an evaluation of reports, notes, data, and other documents to ensure there is an appropriate and sufficient basis for the scientific conclusions.

Technical reviewer is an employee who is a current or previously qualified analyst in the methodology being reviewed that performs a technical review of, and is not an author of, the applicable report or its contents.

Technician (or equivalent role, position, or title as designated by the laboratory director) is an employee who performs analytical techniques on forensic samples under the supervision of a qualified analyst. Technicians do not interpret data, reach conclusions on typing results, or prepare final reports.

Technology is used to describe the type of forensic DNA analysis performed in the laboratory, such as RFLP, STR, YSTR, or mitochondrial DNA.

Test kit is a pre-assembled set of reagents that allows the user to conduct a specific DNA extraction, quantitation or amplification.

Traceability is the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons.

Underlying scientific principle is a rule concerning a natural phenomenon or function that is a part of the basis used to proceed to more detailed scientific functions.

Validation is a process by which a procedure is evaluated to determine its efficacy and reliability for forensic casework analysis and includes the following:

> (1) Developmental validation is the acquisition of test data and determination of conditions and limitations of a new or novel DNA methodology for use on forensic samples.
> (2) Internal validation is an accumulation of test data within the laboratory to demonstrate that established methods and procedures perform as expected in the laboratory.

Vendor laboratory is a governmental or private laboratory that provides DNA analysis services to another laboratory or agency and does not take ownership of the DNA data for purposes of entry into CODIS.

Work product is the material that is generated as a function of analysis, which may include extracts, amplified product and amplification tubes or plates as defined by the laboratory.

3. QUALITY ASSURANCE PROGRAM

STANDARD 3.1 The laboratory shall establish, follow and maintain a documented quality system that is appropriate to the testing activities and is equivalent to or more stringent than what is required by these Standards.

3.1.1 The quality system shall be documented in a manual that includes or references the following elements:

3.1.1.1 Goals and objectives

3.1.1.2 Organization and management

3.1.1.3 Personnel

3.1.1.4 Facilities

3.1.1.5 Evidence control

3.1.1.6 Validation

3.1.1.7 Analytical procedures

3.1.1.8 Equipment calibration and maintenance

3.1.1.9 Reports

3.1.1.10 Review

3.1.1.11 Proficiency testing

3.1.1.12 Corrective action

3.1.1.13 Audits

3.1.1.14 Safety

3.1.1.15 Outsourcing

STANDARD 3.2 The laboratory shall maintain and follow a procedure regarding document retention that specifically addresses proficiency tests, corrective action, audits, training records, continuing education, case files and court testimony monitoring.

STANDARD 3.3 The quality system as applicable to DNA shall be reviewed annually independent of the audit required by Standard 15. The review of the quality system shall be completed under the direction of the technical leader and the approval by the technical leader shall be documented.

4. ORGANIZATION AND MANAGEMENT

STANDARD 4.1 The laboratory shall:

4.1.1 Have a managerial staff with the authority and resources needed to discharge their duties and meet the requirements of the Standards in this document.

4.1.2 Have a technical leader who is accountable for the technical operations. Multi-laboratory systems shall have at least one technical leader.

4.1.3 Have a casework CODIS administrator who is accountable for CODIS on-site at each individual laboratory facility utilizing CODIS.

4.1.4 Have at least two full time employees who are qualified DNA analysts.

4.1.5 Specify and document the responsibility, authority, and interrelation of all personnel who manage, perform or verify work affecting the validity of the DNA analysis.

4.1.6 Have a documented contingency plan that is approved by laboratory management if the technical leader position is vacated.

5. PERSONNEL

STANDARD 5.1 Laboratory personnel shall have the education, training and experience commensurate with the examination and testimony provided. The laboratory shall:

5.1.1 Have a written job description for personnel, that may be augmented by additional documentation, that defines responsibilities, duties and skills.

5.1.2 Have a documented training program for qualifying all analyst/technician(s).

5.1.2.1 The laboratory's training program shall include a training manual covering all DNA analytical procedures that the analyst/technician will perform. Practical exercises shall include the examination of a range of samples routinely encountered in casework.

5.1.2.2 The training program shall teach and assess the technical skills and knowledge required to perform DNA analysis.

5.1.2.2.1 The training program shall require an individual's demonstration of competency. The laboratory shall maintain documentation of the successful completion of such competency test(s).

5.1.2.2.2 When hiring experienced analyst/technician(s), the technical leader shall be responsible for assessing their previous training and ensuring it is adequate and documented. Modification to the training program may be appropriate and shall be documented by the technical leader.

5.1.2.2.3 All analyst/technician(s), regardless of previous experience, shall successfully complete a competency test(s) covering the routine DNA methodologies to be used prior to participating in independent casework analysis.

5.1.3 Have a documented program to ensure technical qualifications are maintained through participation in continuing education.

5.1.3.1 Continuing education: The technical leader, casework CODIS administrator, and analyst(s) shall stay abreast of developments within the field of DNA typing by attending seminars, courses, professional meetings or documented training sessions/classes in relevant subject areas at least once each calendar year. A minimum of eight cumulative hours of continuing education are required annually and shall be documented.

5.1.3.1.1 If continuing education is conducted internally, the title of the program, a record of the presentation, date of the training, attendance list, and the curriculum vitae of the presentor(s) shall be documented and retained by the laboratory.

5.1.3.1.2 If the continuing education is conducted externally, the laboratory shall maintain documentation of attendance through a

mechanism such as certificates, program agenda/syllabus, or travel documentation. Attendance at a regional, national or international conference shall be deemed to provide a minimum of 8 hours of continuing education.

5.1.3.1.3 Programs based on multimedia or internet delivery shall be subject to the approval of the technical leader. Participation in such programs shall be formally recorded and its completion shall be submitted to the technical leader for review and approval. The documentation shall include the time required to complete the program.

5.1.3.2 The laboratory shall have a program approved by the technical leader for the annual review of scientific literature that documents the analysts' ongoing reading of scientific literature. The laboratory shall maintain or have physical or electronic access to a collection of current books, reviewed journals, or other literature applicable to DNA analysis.

5.1.4 Maintain records on the relevant qualifications, training, skills and experience of the technical personnel.

STANDARD 5.2 The technical leader shall meet the following qualifications:

5.2.1 Minimum educational requirements: The technical leader of a laboratory shall have, at a minimum, a Master's degree in a biology-, chemistry- or forensic science- related area and successfully completed 12 semester or equivalent credit hours from a combination of undergraduate and graduate course work covering the following subject areas: biochemistry, genetics, molecular biology, and statistics or population genetics.

5.2.1.1 The 12 semester or equivalent credit hours shall include at least one graduate level course registering three (3) or more semester or equivalent credit hours.

5.2.1.2 The specific subject areas listed in 5.2.1 shall constitute an integral component of any course work used to demonstrate compliance with this Standard.

5.2.1.3 Individuals who have completed course work with titles other than those listed in 5.2.1 shall demonstrate compliance with this Standard through a combination of pertinent materials such as a transcript, syllabus, letter from the instructor or other document that supports the course content.

5.2.1.4 If the degree requirements of section 5.2.1 were waived by the American Society of Crime Laboratory Directors (ASCLD) in accordance

with criteria approved by the Director of the Federal Bureau of Investigation (FBI), such a documented waiver shall be permanent and portable.

5.2.2 Minimum experience requirements: A technical leader of a laboratory shall have three years of forensic DNA laboratory experience obtained at a laboratory where forensic DNA testing was conducted for the identification and evaluation of biological evidence in criminal matters. As of the effective date of this revision, any newly appointed technical leader shall have a minimum of three years of human DNA (current or previous) experience as a qualified analyst on forensic samples. The technical leader shall have previously completed or successfully complete the FBI sponsored auditor training within one year of appointment.

5.2.3 The technical leader shall be responsible for the following:

5.2.3.1 General duties and authority:

5.2.3.1.1 Oversee the technical operations of the laboratory.

5.2.3.1.2 Authority to initiate, suspend and resume DNA analytical operations for the laboratory or an individual.

5.2.3.2 The minimum specific responsibilities to be performed by the technical leader include the following:

5.2.3.2.1 To evaluate and document approval of all validations and methods used by the laboratory and to propose new or modified analytical procedures to be used by analysts.

5.2.3.2.2 To review the academic transcripts and training records for newly qualified analysts and approve their qualifications prior to independent casework analysis and document such review.

5.2.3.2.3 To approve the technical specifications for outsourcing agreements.

5.2.3.2.4 To review internal and external DNA Audit documents and, if applicable, approve corrective action(s), and document such review.

5.2.3.2.5 To review, on an annual basis, the procedures of the laboratory and document such review.

5.2.3.2.6 To review and approve the training, quality assurance and proficiency testing programs in the laboratory.

5.2.4. Accessibility: The technical leader shall be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed. A multi-laboratory system may have one technical leader over a system of separate laboratory facilities. For multi-laboratory systems the technical leader shall conduct a site visit to each laboratory at least semi-annually.

5.2.4.1 The technical leader shall be a full time employee of the laboratory or multi-laboratory system.

5.2.4.1.1 In the event that the technical leader position of a laboratory is vacated and there is no individual in the laboratory or multi-laboratory system who meets the requirements of this standard and serve as a technical leader, the laboratory shall immediately contact the FBI and submit their contingency plan within14 days to the FBI for its approval. Work in progress by the laboratory may be completed during this 14 day period but new casework shall not be started until the plan is approved by the FBI.

5.2.5 Newly appointed technical leaders shall be responsible for the documented review of the following:

5.2.5.1 Validation studies and methodologies currently used by the laboratory; and

5.2.5.2 Educational qualifications and training records of currently qualified analysts.

STANDARD 5.3 The casework CODIS administrator shall be an employee of the laboratory and meet the following qualifications:

5.3.1 Minimum educational requirements: The casework CODIS Administrator shall meet the education requirements for an analyst as defined in Standard 5.4. A casework CODIS Administrator appointed prior to the effective date of this revision shall be deemed to have satisfied the minimum educational requirements; satisfaction of these minimum educational requirements shall be applicable to the specific laboratory the casework CODIS Administrator is employed by prior to the effective date of this revision and shall not be portable.

5.3.2 Minimum experience requirements: A casework CODIS administrator shall be or have been a current or previously qualified DNA analyst as defined in Standard 5.4 with documented mixture interpretation training. A casework CODIS administrator appointed prior to the effective date of this revision who is not or has never been a qualified analyst (with documented training in mixture interpretation) shall be deemed to have satisfied the minimum experience requirements upon completion of FBI sponsored CODIS training; satisfaction of these minimum requirements shall be applicable to the specific laboratory the

casework CODIS administrator is employed by prior to the effective date of this revision and shall not be portable.

5.3.3 Minimum CODIS training requirements. The casework CODIS Administrator shall participate in the FBI sponsored training in CODIS software within six months of assuming CODIS casework administrator duties if the Administrator had not previously attended such training. The casework CODIS Administrator shall successfully complete the FBI sponsored auditor training within one year of assuming their Administrator duties if the Administrator had not previously attended such training.

5.3.4 The casework CODIS Administrator shall be responsible for the following:

5.3.4.1 Administration of the laboratory's local CODIS network.

5.3.4.2. Scheduling and documentation of the CODIS computer training of casework analysts.

5.3.4.3 Assurance that the security of data stored in CODIS is in accordance with state and/or federal law and NDIS operational procedures.

5.3.4.4 Assurance that the quality of data stored in CODIS is in accordance with state and/or federal law and NDIS operational procedures.

5.3.4.5 Assurance that matches are dispositioned in accordance with NDIS operational procedures.

5.3.5 The casework CODIS Administrator shall be authorized to terminate an analyst's or laboratory's participation in CODIS until the reliability and security of the computer data can be assured in the event an issue with the data is identified.

5.3.6 A laboratory shall not upload DNA profiles to NDIS in the event that the casework CODIS Administrator position is unoccupied.

STANDARD 5.4 The analyst shall be an employee of the laboratory and meet the following qualifications:

5.4.1 Minimum educational requirements: The analyst shall have a bachelor's (or its equivalent) or an advanced degree in a biology-, chemistry-, or forensic science-, related area and shall have successfully completed course work (graduate or undergraduate level) covering the following subject areas:

biochemistry, genetics, molecular biology; and course work and/or training in statistics and/or population genetics as it applies to forensic DNA analysis.

5.4.1.1. The specific subject areas listed in Standard 5.4.1. shall be an integral component of any coursework for compliance with this Standard.

5.4.1.2. Analysts appointed or hired after the effective date of these revisions shall have a minimum of nine cumulative semester hours or equivalent that cover the required subject areas.

5.4.1.3. Analysts who have completed course work with titles other than those listed in 5.4.1 above shall demonstrate compliance with this Standard through a combination of pertinent materials, such as a transcript, syllabus, letter from the instructor, or other document that supports the course content. The technical leader shall document approval of compliance with this Standard.

5.4.2 Minimum experience requirements: The analyst shall have six (6) months of forensic human DNA laboratory experience. If prior forensic human DNA laboratory experience is accepted by a laboratory, the prior experience shall be documented and augmented by additional training, as needed, in the analytical methodologies, platforms and interpretations of human DNA results used by the laboratory.

5.4.2.1 The analyst shall complete the analysis of a range of samples routinely encountered in forensic casework prior to independent work using DNA technology.

5.4.2.2 The analyst shall successfully complete a competency test before beginning independent DNA analysis.

STANDARD 5.5 The technician shall meet the following qualifications:

5.5.1 Documented training specific to their job function(s).

5.5.2 Successful completion of a competency test before participating in DNA analysis on evidence.

STANDARD 5.6 Laboratory technical support personnel shall have documented training specific to their job function(s).

6. FACILITIES

STANDARD 6.1 The laboratory shall have a facility that is designed to ensure the integrity of the analyses and the evidence.

6.1.1 Access to the laboratory shall be controlled and limited in a manner to prevent access by unauthorized personnel. All exterior entrance/exit points require security control. The distribution of all keys, combinations, etc., shall be documented and limited to the personnel designated by laboratory management.

6.1.2 Except as provided in 6.1.4., techniques performed prior to PCR amplification such as evidence examinations, DNA extractions, and PCR setup shall be conducted at separate times or in separate spaces from each other. Standard 6.1.4 is applicable if robotic workstations are used by the laboratory.

6.1.3 Except as provided in 6.1.4., amplified DNA product, including real time PCR, shall be generated, processed and maintained in a room(s) separate from the evidence examination, DNA extractions and PCR setup areas. The doors between rooms containing amplified DNA and other areas shall remain closed.

6.1.4 A robotic workstation may be used to carry out DNA extraction, quantitation, PCR setup, and/or amplification in a single room, provided that the analytical process has been validated in accordance with Standard 8. If the robot performs analysis through amplification, the robot shall be housed in a separate room from that used for initial evidence examinations.

6.1.5 The laboratory shall have and follow written procedures for cleaning and decontaminating facilities and equipment.

7. EVIDENCE CONTROL

STANDARD 7.1 The laboratory shall have and follow a documented evidence control system to ensure the integrity of physical evidence.

7.1.1 Evidence shall be marked with a unique identifier on the evidence package. The laboratory shall clearly define what constitutes evidence and what constitutes work product. The laboratory shall have and follow a method to distinguish each sample throughout processing (such as plate or rack mapping) that may not require the assignment of unique identifiers or individual evidence seals for each specimen.

7.1.2 Chain of custody for all evidence shall be documented and maintained in hard or electronic format. The chain of custody shall include the signature, initials or electronic equivalent of each individual receiving or transferring the evidence, the corresponding date for each transfer, and the evidentiary item(s) transferred.

7.1.3 The laboratory shall have and follow documented procedures designed to minimize loss, contamination, and/or deleterious change of evidence and work product in progress.

7.1.4 The laboratory shall have secure, controlled access areas for evidence storage and work product in progress.

STANDARD 7.2 Where possible, the laboratory shall retain or return a portion of the evidence sample or extract.

STANDARD 7.3 The laboratory shall have and follow a documented policy for the disposition of evidence that includes a policy on sample consumption.

8. VALIDATION

STANDARD 8.1 The laboratory shall use validated methodologies for DNA analyses. There are two types of validations: developmental and internal.

STANDARD 8.2 Developmental validation shall precede the use of a novel methodology for forensic DNA analysis.

8.2.1 Developmental validation studies shall include, where applicable, characterization of the genetic marker, species specificity, sensitivity studies, stability studies, reproducibility, case-type samples, population studies, mixture studies, precision and accuracy studies, and PCR-based studies. PCR-based studies include reaction conditions, assessment of differential and preferential amplification, effects of multiplexing, assessment of appropriate controls, and product detection studies. All validation studies shall be documented.

8.2.2 Peer-reviewed publication of the underlying scientific principle(s) of a technology shall be required.

STANDARD 8.3 Except as provided in Standard 8.3.1.1, internal validation of all manual and robotic methods shall be conducted by each laboratory and reviewed and approved by the laboratory's technical leader prior to using a procedure for forensic applications.

8.3.1 Internal validation studies conducted after the date of this revision shall include as applicable: known and non-probative evidence samples or mock evidence samples, reproducibility and precision, sensitivity and stochastic studies, mixture studies, and contamination assessment. Internal validation studies shall be documented and summarized. The technical leader shall approve the internal validation studies.

8.3.1.1 Internal validation data may be shared by all locations in a multi-laboratory system. Each laboratory in a multi-laboratory system shall complete, document and maintain applicable precision, sensitivity, and contamination assessment studies. The summary of the validation data shall be available at each site.

8.3.2 Internal validation shall define quality assurance parameters and interpretation guidelines, including as applicable, guidelines for mixture interpretation.

8.3.3 A complete change of detection platform or test kit (or laboratory assembled equivalent) shall require internal validation studies.

STANDARD 8.4 Before the introduction of a methodology into the laboratory, the analyst or examination team shall successfully complete a competency test to the extent of his/her/their participation in casework analyses.

STANDARD 8.5 The performance of a modified procedure shall be evaluated by comparison with the original procedure using similar DNA samples.

STANDARD 8.6 Each additional critical instrument shall require a performance check. Modifications to an instrument, such as a detection platform, that do not affect the analytical portion of the instrument shall require a performance check.

STANDARD 8.7 Modifications to software, such as an upgrade, shall require a performance check prior to implementation. New software or significant software changes that may impact interpretation or the analytical process shall require a validation prior to implementation.

9. ANALYTICAL PROCEDURES

STANDARD 9.1 The laboratory shall have and follow written analytical procedures approved by the technical leader. The standard operating procedures are to be reviewed annually by the technical leader independent of the audit required by Standard 15 and this review shall be documented.

9.1.1 The laboratory shall have and follow a standard operating procedure for each analytical method used by the laboratory. The procedures shall specify reagents, sample preparation, extraction methods (to include differential extraction of nuclear DNA samples with adequate amount of sperm), equipment, and controls which are standard for DNA analysis and data interpretation.

STANDARD 9.2 The laboratory shall use reagents that are suitable for the methods employed.

9.2.1 The laboratory shall have written procedures for documenting commercial reagents and for the formulation of in-house reagents.

9.2.2 Commercial reagents shall be labeled with the identity of the reagent and the expiration date as provided by the manufacturer or as determined by the laboratory.

9.2.3 In-house reagents shall be labeled with the identity of the reagent, the date of preparation and/or expiration, and the identity of the individual preparing the reagent.

STANDARD 9.3 The laboratory shall identify critical reagents and evaluate them prior to use in casework. These critical reagents shall include but are not limited to the following:

9.3.1 Test kits or systems for performing quantitative PCR and genetic typing

9.3.2 Thermostable DNA polymerase, primer sets and allelic ladders used for genetic analysis that are not tested as test kit components under Standard 9.3.1.

STANDARD 9.4 The laboratory shall quantify the amount of human DNA in forensic samples prior to nuclear DNA amplification. Quantitation of human DNA is not required for casework reference samples if the laboratory has a validated system that has been demonstrated to reproducibly and reliably yield successful DNA amplification and typing without prior quantitation.

STANDARD 9.5 The laboratory shall monitor the analytical procedures using the following controls and standards.

9.5.1 Where quantitation is used, quantitation standards shall be used.

9.5.2 Positive and negative amplification controls associated with samples being typed shall be amplified concurrently with the samples at all loci and with the same primers as the forensic samples. All samples typed shall also have the corresponding amplification controls typed.

9.5.3 Reagent blank controls associated with each extraction set being analyzed shall be:

9.5.3.1 Extracted concurrently;

9.5.3.2 Amplified utilizing the same primers, instrument model and concentration conditions as required by the sample(s) containing the least amount of DNA; and

9.5.3.3 Typed utilizing the same instrument model, injection conditions and most sensitive volume conditions of the extraction set.

9.5.4 Allelic ladders and internal size makers for variable number tandem repeat sequence PCR based systems.

9.5.5 The laboratory shall check its DNA procedures annually or whenever substantial changes are made to a procedure against an appropriate and available NIST standard reference material or standard traceable to a NIST standard.

STANDARD 9.6 The laboratory shall have and follow written guidelines for the interpretation of data.

9.6.1 The laboratory shall verify that all control results meet the laboratory's interpretation guidelines for all reported results.

9.6.2 For a given population(s), the statistical interpretation of autosomal loci shall be made following the recommendations 4.1, 4.2 or 4.3 as deemed applicable of the National Research Council report entitled "The Evaluation of Forensic DNA Evidence" (1996) and/or court directed method. These calculations shall be derived from a documented population database appropriate for the calculation.

9.6.3 A laboratory performing genetic analyses not addressed by Standard 9.6.2, such as Y-chromosome or mtDNA typing shall have and follow documented statistical interpretation guidelines specific for such testing.

9.6.4 Laboratories analyzing forensic samples shall have and follow a documented procedure for mixture interpretation that addresses major and minor contributors, inclusions and exclusions, and policies for the reporting of results and statistics.

STANDARD 9.7 The laboratory shall have and follow a documented policy for the detection and control of contamination.

10. EQUIPMENT CALIBRATION AND MAINTENANCE

STANDARD 10.1 The laboratory shall use equipment suitable for the methods employed.

STANDARD 10.2 The laboratory shall have and follow a documented program for conducting performance checks and calibration of instruments and equipment.

10.2.1 At a minimum, the following critical instruments or equipment shall require annual performance checks:

10.2.1.1 Thermometer traceable to national or international standard(s) that is used for conducting performance checks.

10.2.1.2 Balance/scale

10.2.1.3 Thermal Cycler temperature verification system

10.2.1.4 Thermal Cycler including quantitative-PCR

10.2.1.5 Electrophoresis detection systems

10.2.1.6 Robotic systems

10.2.1.7 Genetic Analyzers

10.2.1.8 Mechanical pipettes.

STANDARD 10.3 The laboratory shall have a schedule and follow a documented program to ensure that instruments and equipment are properly maintained. The laboratory shall retain documentation of maintenance, service or calibration.

STANDARD 10.4 New critical instruments and equipment, or critical instruments and equipment that have undergone repair, service or calibration, shall undergo a performance check before use in casework analysis.

10.4.1 At a minimum, the following critical equipment shall undergo a performance check following repair, service or calibration:

10.4.1.1 Electrophoresis detection systems

10.4.1.2 Robotic systems

10.4.1.3 Genetic Analyzers

10.4.1.4 Thermal cycler including quantitative-PCR

11. REPORTS

STANDARD 11.1 The laboratory shall have and follow written procedures for taking and maintaining casework notes to support the conclusions drawn in laboratory reports. The laboratory shall maintain all analytical documentation generated by analysts related to case analyses. The laboratory shall retain, in hard or electronic format, sufficient documentation for each technical analysis to support the report conclusions such that another qualified individual could evaluate and interpret the data.

STANDARD 11.2 Casework reports shall include the following elements:

11.2.1 Case identifier;

11.2.2 Description of evidence examined;

11.2.3 A description of the technology;

11.2.4 Locus or amplification system;

11.2.5 Results and/or conclusions;

11.2.6 A quantitative or qualitative interpretative statement;

11.2.7 Date issued;

11.2.8 Disposition of evidence; and

11.2.9 A signature and title, or equivalent identification, of the person accepting responsibility for the content of the report.

STANDARD 11.3 Except as otherwise provided by state or federal law, reports, case files, DNA records and databases shall be confidential.

11.3.1 The laboratory shall have and follow written procedures to ensure the privacy of the reports, case files, DNA records and databases.

11.3.2 The laboratory shall have and follow written procedures for the release of reports, case files, DNA records and databases in accordance with applicable state or federal law.

11.3.3 Personally identifiable information shall only be released in accordance with applicable state and federal law.

12. REVIEW

STANDARD 12.1 The laboratory shall conduct and document administrative and technical reviews of all case files and reports to ensure conclusions and supporting data are reasonable and within the constraints of scientific knowledge. The review of data generated external to the laboratory is governed by Standard 17.

12.1.1 An individual conducting technical reviews shall be or have been an analyst qualified in the methodology being reviewed.

STANDARD 12.2 Completion of the technical review shall be documented and the technical review of forensic casework shall include the following elements:

12.2.1 A review of all case notes, all worksheets, and the electronic data (or printed electropherograms or images) supporting the conclusions.

12.2.2 A review of all DNA types to verify that they are supported by the raw or analyzed data (electropherograms or images).

12.2.3 A review of all profiles to verify correct inclusions and exclusions (if applicable) as well as a review of any inconclusive result for compliance with laboratory guidelines.

12.2.4 A review of all controls, internal lane standards and allelic ladders to verify that the expected results were obtained.

12.2.5 A review of statistical analysis, if applicable.

12.2.6 A review of the final report's content to verify that the results/conclusions are supported by the data. The report shall address each tested item or its probative fraction.

12.2.7 Verification that all profiles entered into CODIS are eligible, have the correct DNA types and correct specimen category

12.2.7.1 Prior to upload to or search of SDIS, verification of the following criteria for DNA profiles: eligibility for CODIS, correct DNA types, and appropriate specimen category.

12.2.7.2 For entry into a searchable category at SDIS, verification of the following criteria for DNA profiles by two concordant assessments by a qualified analyst or technical reviewer: eligibility for CODIS; correct DNA types; and appropriate specimen category.

STANDARD 12.3 The administrative review shall include the following elements, any or all of which may be included within the technical review:

12.3.1 A review of the case file and final report for clerical errors and that information specified in Standard 11.2 is present and accurate.

12.3.2 A review of chain of custody and disposition of evidence.

12.3.3 A procedure to document the completion of the administrative review.

STANDARD 12.4 The laboratory shall document the elements of a technical and administrative review. Case files shall be reviewed and documented according to the laboratory's procedure.

STANDARD 12.5 The laboratory shall have and follow a documented procedure to address unresolved discrepant conclusions between analysts and reviewer(s).

STANDARD 12.6 The laboratory shall have and follow a documented procedure for the verification and resolution of database matches.

STANDARD 12.7 The laboratory shall have and follow a program that documents the annual monitoring of the testimony of each analyst.

13. PROFICIENCY TESTING

STANDARD 13.1 Analysts, technical reviewers, technicians, and other personnel designated by the technical leader, shall undergo semi-annual external proficiency testing in each technology performed to the full extent in which they participate in casework. Semi-annual is used to describe an event that takes place two times during one calendar year, with the first event taking place in the first six months of that year and the second event taking place in the second six months of that year and where the interval between the two events is at least four months and not more than eight months. Such external proficiency testing shall be an open proficiency testing program and shall be submitted to the proficiency testing provider in order to be included in the provider's published external summary report.

13.1.1 Individuals routinely utilizing both manual and automated methods shall be proficiency tested in each at least once per year to the full extent in which they participate in casework.

13.1.2 Newly qualified individuals shall enter the external proficiency testing program within six months of the date of their qualification.

13.1.3 For purposes of tracking compliance with the semi-annual proficiency testing requirement, the laboratory shall define, document and consistently use the date that the proficiency test is performed as the received date, assigned date, submitted date, or the due date.

13.1.4 Except as provided in Standard 13.1.4.1, each analyst shall be assigned and complete his/her own external proficiency test.

13.1.4.1 Laboratories that use a team approach to casework examination may do so on external proficiency tests. However, all analysts, technicians, and technical reviewers shall be proficiency tested at least once per year in each of the DNA technologies, including test kits for DNA typing, and each platform in which they perform forensic DNA analysis.

13.1.5 Typing of all CODIS core loci or CODIS core sequence ranges shall be attempted for each technology performed.

13.1.6 The laboratory shall maintain the following records for proficiency tests:

13.1.6.1 The test set identifier,
13.1.6.2 Identity of the analyst, and other participants, if applicable,
13.1.6.3 Date of analysis and completion,
13.1.6.4 Copies of all data and notes supporting the conclusions,
13.1.6.5 The proficiency test results,
13.1.6.6 Any discrepancies noted, and
13.1.6.7 Corrective actions taken.

13.1.7 The laboratory shall include, at a minimum, the following criteria for evaluating proficiency test results:

13.1.7.1 Inclusions and exclusions as well as all reported genotypes and/or phenotypes are correct or incorrect according to consensus results or are within the laboratory's interpretation guidelines.

13.1.7.2 All results reported as inconclusive or not interpretable are consistent with written laboratory guidelines.

13.1.7.2.1 The technical leader shall review any inconclusive result for compliance with laboratory guidelines.

13.1.7.3 All discrepancies/errors and subsequent corrective actions shall be documented.

13.1.7.4 All final reports are graded as satisfactory or unsatisfactory.

13.1.7.4.1 A satisfactory grade is attained when there are no analytical errors for the DNA profile typing data.

13.1.7.4.1.1 Administrative errors and corrective actions, as applicable, shall be documented.

13.1.8 All proficiency test participants shall be informed of his/her final test results and this notification shall be documented.

13.1.9 The technical leader shall be informed of the results of all participants and this notification shall be documented. The technical leader shall inform the casework CODIS administrator of all non-administrative discrepancies that affect the typing results and/or conclusions at the time of discovery.

STANDARD 13.2 The laboratory shall use an external proficiency test provider that is in compliance with the current proficiency testing manufacturing guidelines established by the American Society of Crime Laboratory Directors/ Laboratory Accreditation Board or be in compliance with the current International Organization for Standardization.

14. CORRECTIVE ACTION

STANDARD 14.1 The laboratory shall establish and follow a corrective action plan to address when discrepancies are detected in proficiency tests and casework analysis. A laboratory corrective action plan shall define what level/type of discrepancies are applicable to this practice and identify (when possible) the cause, effect of the discrepancy, corrective actions taken and preventative measures taken (where applicable) to minimize its reoccurrence. Documentation of all corrective actions shall be maintained in accordance with Standard 3.2.

STANDARD 14.2 Corrective actions shall not be implemented without the documented approval of the technical leader.

15. AUDITS

STANDARD 15.1 The laboratory shall be audited annually in accordance with these standards. The annual audits shall occur every calendar year and shall be at least 6 months and no more than 18 months apart.

STANDARD 15.2 At least once every two years, an external audit shall be conducted by an audit team comprised of qualified auditors from a second agency(ies) and having at least one team member who is or has been previously qualified in the laboratory's current DNA technologies and platform.

> 15.2.1 Each analyst, casework CODIS administrator and technical leader shall have his/her education, experience and training qualifications evaluated and approved during two successive, separate external audits conducted after July 1, 2004. Approval of an individual's education, experience and training qualifications shall be documented in the audit document.
>
> 15.2.2 Each validation study shall be evaluated and approved during one external audit. Approved validation studies shall be documented in the audit document.

STANDARD 15.3. For internal audits, the auditor or audit team shall have the following expertise: currently qualified auditor and currently or previously qualified as an analyst in the laboratory's current DNA technologies and platform.

STANDARD 15.4 Internal and external audits shall be conducted utilizing the FBI DNA Quality Assurance Standards Audit Document.

STANDARD 15.5 Internal and external DNA Audit documents and, if applicable, corrective action(s) shall be submitted to the technical leader for review to ensure that findings, if any, were appropriately addressed.

> 15.5.1 For NDIS participating laboratories, all external audit documentation and laboratory responses shall be provided to the FBI within 30 days of laboratory receipt of the audit documents or report.

STANDARD 15.6 Internal and external audit documentation shall be retained and available for inspection during subsequent audits.

16. SAFETY

STANDARD 16.1 The laboratory shall have and follow a documented environmental health and safety program. This program shall include the following:

16.1.1 A blood borne pathogen and chemical hygiene plan

16.1.2 Documented training on the blood borne pathogen and chemical hygiene plan.

STANDARD 16.2 The laboratory's environmental health and safety program shall be reviewed once each calendar year and such review shall be documented.

STANDARD 17. OUTSOURCING

STANDARD 17.1 A vendor laboratory performing forensic DNA analysis shall comply with these Standards and the accreditation requirements of federal law.

17.1.1 An NDIS participating laboratory that outsources DNA sample(s) to a vendor laboratory to generate DNA data that will be entered into CODIS shall require the vendor laboratory to provide documentation of compliance with these Standards and the accreditation requirements of federal law. The NDIS participating laboratory shall maintain such documentation.

STANDARD 17.2 Except as provided in Standard 17.2.1, an NDIS participating laboratory's technical leader shall document approval of the technical specifications of the outsourcing agreement with a vendor laboratory before it is awarded. Such documentation shall be maintained by the NDIS participating laboratory.

17.2.1 A vendor laboratory that is performing forensic DNA analysis for a law enforcement agency or other entity and generating DNA data that may be entered into or searched in CODIS shall not initiate analysis for a specific case or set of cases until documented approval has been obtained from the appropriate NDIS participating laboratory's technical leader of acceptance of ownership of the DNA data.

STANDARD 17.3 An NDIS participating laboratory shall not upload or accept DNA data for upload to or search in CODIS from any vendor laboratory or agency without the documented prior approval of the technical specifications of the outsourcing agreement and/or documented approval of acceptance of ownership of the DNA data by the NDIS participating laboratory's technical leader.

STANDARD 17.4 An NDIS participating laboratory shall have and follow a procedure to verify the integrity of the DNA data received through the performance of the technical review of DNA data from a vendor laboratory.

STANDARD 17.5 Prior to the upload or search of DNA data to SDIS, the technical review of a vendor laboratory's DNA data shall be performed by an analyst or technical reviewer employed by the NDIS participating laboratory who is qualified or previously qualified in the technology, platform and typing amplification test kit used to generate the data and participates in the laboratory's proficiency testing program.

17.5.1 The technical review shall include the following elements:

17.5.1.1 A review of all DNA types to verify that they are supported by the raw and/or analyzed data (electropherograms or images).

17.5.1.2 A review of all associated controls, internal lane standards and allelic ladders to verify that the expected results were obtained.

17.5.1.3 A review of the final report (if provided) to verify that the results/conclusions are supported by the data. The report shall address each tested items (or its probative fractions) submitted to the vendor laboratory.

17.5.1.4 Verification of the DNA types, eligibility, and the correct specimen category for entry into CODIS.

STANDARD 17.6 An NDIS participating laboratory or multi-laboratory system outsourcing DNA sample(s) to a vendor laboratory or accepting ownership of DNA data from a vendor laboratory shall have and follow a procedure to perform an on-site visit(s) of the vendor laboratory. This procedure shall include, at a minimum, the following elements:

17.6.1 A documented initial on-site visit prior to the vendor laboratory's beginning of casework analysis for the laboratory.

17.6.1.1 The on-site visit shall be performed by the technical leader, or a designated employee of the NDIS participating laboratory who is a qualified or previously qualified DNA analyst in the technology, platform and typing amplification test kit, used to generate the DNA data.

17.6.2 If the outsourcing agreement extends beyond one year, an annual on-site visit shall be required. Each annual on-site visit shall occur every calendar year and shall be at least 6 months and no more than 18 months apart.

17.6.2.1 An NDIS participating laboratory may accept an on-site visit conducted by another NDIS participating laboratory using the same technology, platform and typing amplification test kit, for the generation of the DNA data and shall document the review and approval of such on-site visit.